AEGIS LIFESCIENCES
PROTECTION THROUGH PERFECTION

CE 2460 ISO 13485

EC Declaration of Conformity

(Issued according to Medical Devices Directive 93/42/EEC, as last amended by directive 2007/47/EC)

We hereby declare that the devices mentioned below fall within class III and meet the provisions of Medical Devices Directive of the European Union, 93/42/EEC as last amended under directive 2007/47/EC. We also declare that conformity assessment procedure is carried out according to annex II of the directive and implemented quality management system, complying ISO 13485:2016 & EN ISO 13485:2016. The manufacturer is solely responsible for the declaration of conformity.

Manufacturer : AEGIS LIFESCIENCES PVT. LTD.
Address : 215/216, Mahagujarat Industrial Estate-382 213, Ahmedabad, Gujarat, India.
EUDAMED SRN Number/Actor ID : IN-MF-000024058

EC representative : Obelis S.A
Address : Bd. General Wahis 53, 1030 Brussels, Belgium.
EUDAMED SRN Number/Actor ID : BE-AR-000000106

Product Name : SURGISPON®
Generic Name : Gelatin based, sterile, absorbable, haemostatic sponge for surgical use
Intended Purpose/Use : The above mentioned product is gelatin based, sterile, absorbable, topical haemostatic for use in various surgical procedures where traditional haemostatic is difficult or impractical and use of other non-absorbable materials is undesirable. It is manufactured from highly purified pharmaceutical grade gelatin.
GMND Code : 48170
Class : III (Rule 17 of Annex IX, MDD 93/42/EEC)
Basic UDI-DI : 890603845AGSNM

Notified Bodies	: Notified Body Name	DNV Product Assurance AS	CE Certificates
	: Identification number of the notified body	NB 2460	
	: Notified Body Name	BSI Group The Netherlands B.V.	ISO 13485:2016 & EN ISO 13485:2016 Certificate
	: Identification number of the notified body	NB 2797	

Sizes/Model/Type As given in below table.

S. No.	Product Id	Product Name	Dimensions (mm)
1.	SSP-101010	DENTAL CUBES	10 x 10 x 10
2.	SSP-202007	DENTAL	20 x 20 x 07
3.	SSP-1208	DENTAL TAMPON	12 x 08 Ø

SURGISPON® - SSP

Standards applied: EN 556-1:2001, EN 1041:2008, EN ISO 10993-1:2009, EN ISO 10993-3:2014, EN ISO 10993-4:2009 EN ISO 10993-5:2009, EN ISO 10993-6:2009, EN ISO 10993-11:2018, EN ISO 10993-12:2021, EN ISO 10993-18:2020, EN ISO 11137-1:2015, EN ISO 11137-2:2015, EN ISO 11607-1:2020, EN ISO 11607-2:2020, EN ISO 11737-1:2018, EN ISO 11737-2:2020, EN ISO 13485:2016, EN ISO 14155:2020, EN ISO 14971:2019, EN ISO 15223-1:2021, EN ISO 22442-1:2020, EN ISO 22442-2:2020, EN ISO 22442-3: 2007, ISO 10993-10: 2021, ISO 14644 – 1: 2015, ISO 14644-2:2015, UNITED STATES PHARMACOPOEIA – 43.

Conformance Certificate details:

CE Certificate	**: 241608-2017-CE-IND-NA-PS Rev. 2.0**	**Valid Until: 27 May 2024**
Design Approval Certificate	**: 242606-2017-CE-IND-NA-PS Rev. 2.0**	**Valid Until: 27 May 2024**
ISO 13485:2016 & EN ISO 13485:2016 Certificate	**: MD 766456**	**Expiry Date: 2022-10-24**

For Aegis Lifesciences Pvt. Ltd.
Authorized Signatory:

AEGIS LIFESCIENCES PVT. LTD.

Name : **Mr. Bhavin Trivedi**
Position : **Authorized Signatory**
Date : 06/09/2022
Place : Ahmedabad, India.

AEGIS LIFESCIENCES PVT. LTD. 215/216, Mahagujarat Estate, Gam: Moraiya, Tal. Sanand, Dist.: Ahmedabad-382213.
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